IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division



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| **ELLEN R. DUNSTON,** | ) | |
| **Plaintiff,** | ) | |
| | ) | |
| **v.** | ) | **Civil Action No. 1:09cv1369** |
| | ) | |
| **CECIL HUANG, M.D., *et al.*,** | ) | |
| **Defendants.** | ) | |

## MEMORANDUM OPINION

At issue on defendants' motion in this diversity medical malpractice case is whether the expert opinion and testimony of Stephen E. Abram, M.D.—one of plaintiff's designated standard of care experts—must be excluded at trial. Specifically, defendants first argue that Dr. Abram does not have an "active clinical practice in either the defendant's specialty or a related field of medicine," as required by Virginia Code § 8.01-581.20, and thus may not testify as to (i) the standard of care governing appropriate treatment decisions for pain associated with shingles, and (ii) the standard of care on obtaining informed consent for epidural steroid injections. In addition, defendants argue that Dr. Abram may not testify as to the cause of plaintiff's injury because his, Dr. Abram's, causation theory fails to meet the requirements of Rule 702, Fed. R. Evid., and the standard set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The parties fully briefed and argued the issues at a May 21, 2010 hearing, following which the matter was resolved from the Bench. This Memorandum Opinion memorializes and further elucidates the Bench ruling denying defendants' motion to exclude.

I.[1]

On December 14, 2009, plaintiff filed a complaint alleging a medical malpractice claim against (i) Loudon Anesthesia Associates, L.L.C., d/b/a Loudon Interventional Pain Center ("LIPC"), and (ii) Dr. Cecil Huang, an LIPC employee. Specifically, plaintiff alleged that on June 1, 2006, she sought treatment from defendants for pain associated with acute herpes zoster, commonly known as shingles. In response, Dr. Huang gave plaintiff a thoracic transforaminal epidural steroid injection. Before doing so, however, Dr. Huang allegedly failed to explain the additional risks associated with an epidural steroid injection over an injection without particulate steroids—in particular, the risk of paralysis—and thus did not obtain informed consent. Accordingly, plaintiff asserts that Dr. Huang negligently breached the applicable standard of care in the following respects:

a. Dr. Huang failed to perform the proper and appropriate procedure for Ms. Dunston's condition.
b. Dr. Huang failed to properly [sic[2]] obtain informed consent for the procedure he did perform.
c. Dr. Huang failed to take appropriate precautions before performing the procedure.
d. Dr. Huang failed to properly [sic] perform the procedure.
e. Dr. Huang failed to appropriately [sic] monitor Ms. Dunston's condition while a patient of the defendants on June 1, 2006.

Compl. ¶ 31. The first two alleged breaches are the subject of Dr. Abram's testimony and the motion at bar. According to the complaint, immediately after receiving the injection plaintiff

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[1] The facts stated herein are derived from the complaint and exhibits submitted in relation to the motion at bar.

[2] *See* Judge T.S. Ellis, III, *In Memoriam: Lewis F. Powell, Jr.*, 112 Harv. L. Rev. 589, 595 (1999) ("And, like many who live by the written word, [Justice Powell] had some pet peeves, split infinitives and beginning sentences with 'however' chief among them.").

suffered (i) chest and arm pain, (ii) a rash on her back, and (iii) numbness in her right leg, and accordingly was transported to Loudon Hospital. Plaintiff alleges that as a proximate result of the injection, she (i) is permanently paralyzed from the chest down and confined to a wheelchair, (ii) has been hospitalized on numerous occasions, and (iii) requires the aid of a nurse when not hospitalized.

In support of these allegations, plaintiff intends to offer at trial the opinion and testimony of Dr. Abram relating to standard of care and causation. With respect to standard of care, it is important to note that Dr. Abram does not criticize the manner in which Dr. Huang administered the thoracic transforaminal epidural steroid injection;[3] rather, Dr. Abram's opinion is limited to Dr. Huang's alleged breach of the standard of care in (i) deciding to perform a thoracic transforaminal epidural steroid injection instead of a different, appropriate procedure, and (ii) purportedly failing to obtain informed consent. More precisely, Dr. Abram states in his expert report that

> [a]t the time Dr. Huang performed the procedure on Ms. Dunston, the risk of paraplegia following transforaminal epidural steroid injections was recognized. The standard of care required Dr. Huang to inform Ms. Dunston of the additional risks involved with the performance of a transforaminal epidural steroid injection, which he did not do.
>
> Dr. Huang's treatment further fell below the standard of care by performing a transforaminal epidural steroid injection for treatment of acute herpes zoster. No evidence, either in practice or literature, supports the use of injection of steroids rather than local anesthetic alone for this indication. A transforaminal epidural, paravertebral nerve root block, interlaminar epidural or

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[3] *See* Defs.' Ex. 1, at 11-12 (confirming that "[a]s far as the technical performance of the procedure itself or the injection by Dr. Huang, you have no criticism of that"). In the course of the May 21, 2010 hearing, plaintiff's counsel represented that another expert witness, whose testimony and qualifications are not at issue here, would testify as to the applicable standard of care relating to the technical performance of the thoracic transforaminal epidural steroid injection on plaintiff. *See* Transcript at 6 (May 21, 2010).

> intercostal nerve block performed with local anesthetic but without particulate corticosteroids would have been acceptable practice and would not have resulted in the injury suffered by Ms. Dunston.

Pl.'s Ex. C.

Dr. Abram also offers an expert opinion on the cause of plaintiff's injury. In this regard, Dr. Abram states that "[d]uring the injection, Ms. Dunston experienced an ischemic lesion to her spinal cord due to the particulate matter in the steroid fluid Dr. Huang used. . . . The particulate matter effectively occluded the smaller arterial supply to an area of Ms. Dunston's spinal cord causing her spinal cord injury." *Id.*

Dr. Abram is a board-certified anesthesiologist with a certificate of added qualifications in pain medicine. Currently, he serves on the anesthesiology faculty of the Medical College of Wisconsin, where he is the director of the pain clinic. Although Dr. Abram is not licensed to practice medicine in Virginia, the Virginia Department of Health Professions has determined that "Dr. Abram's credentials meet the educational and examination requirements for licensure in Virginia." Pl.'s Ex. B. Since 2005, Dr. Abram has practiced exclusively in pain management, which includes the treatment of patients with a variety of types of pain, including pain associated with shingles. More specifically, between 2005 and 2007, Dr. Abram "participated in treating patients with acute herpes zoster"—including "the training of pain fellows and residents" generally, and the "supervis[ion] [of] pain fellows and residents about the treatment of acute herpes zoster" specifically—with the practice "usually see[ing] between two to three patients a year with acute herpes zoster." Pl.s' Ex. A ¶¶ 5, 6. Although Dr. Abram does perform transforaminal epidural steroid injections, albeit "judiciously because of the increased risks," *id.* ¶ 17, he has never performed a *thoracic* transforaminal epidural steroid injection, the specific

procedure Dr. Huang performed on plaintiff, *see* Defs.' Ex. 1, at 18. Instead, at the thoracic level Dr. Abram performs interlaminar epidurals, and in fact performed this procedure between 2005 and 2007. Consistent with the fact that he has never performed a thoracic transforaminal epidural steroid injection, Dr. Abram has never obtained informed consent for the performance of this procedure. Yet, Dr. Abram has obtained informed consent for the performance of other types of steroid injections. *See* Defs.' Ex. 1, at 31-33.

**II.**

Under Virginia law, it is well-settled that a plaintiff bringing a claim for medical malpractice must establish the requisite standard of care and prove that the defendant deviated from the standard of care, thereby causing damage. *See Raines v. Lutz*, 341 S.E.2d 194, 196 (Va. 1986). The Virginia Code defines "standard of care" to be "that degree of skill and diligence practiced by a reasonably prudent practitioner in the field of practice or specialty in this Commonwealth." Va. Code § 8.01-581.20(A). Where, as here, the alleged negligent acts or omissions do not "clearly lie within the range of a jury's common knowledge and experience," it is necessary for the plaintiff to produce expert testimony "to assist a jury in determining a health care provider's appropriate standard of care and whether there has been a deviation from that standard." *Dickerson v. Fatehi*, 484 S.E.2d 880, 881-82 (Va. 1997).

The admissibility of expert testimony concerning standard of care in medical malpractice actions is governed by Virginia Code § 8.01-581.20(A). This statutory provision first states that "any physician who is licensed in some other state of the United States and meets the educational and examination requirements for licensure in Virginia" is "presumed to know the statewide standard of care in the specialty or field of medicine in which he is qualified and certified." Va.

Code § 8.01-581.20(A). Yet, even where the statutory presumption applies, the proffered expert witness must satisfy two additional requirements, namely that he demonstrate (1) "expert knowledge of the standards of the defendant's specialty and of what conduct conforms or fails to conform to those standards," and (2) an "active clinical practice in either the defendant's specialty or a related field of medicine within one year of the date of the alleged act or omission forming the basis of the action." *Id.*; *see also Jackson v. Qureshi*, 671 S.E.2d 163, 167 (Va. 2009) (explaining statutory requirements). The Supreme Court of Virginia refers to these two distinct statutory requirements as the "knowledge" requirement and the "active clinical practice" requirement. *See, e.g., Wright v. Kaye*, 593 S.E.2d 307, 311 (Va. 2005). *See generally* 14B Michie's Jurisprudence, Physicians and Surgeons § 18 (explicating statutory requirements and citing cases). In this case, defendants move for exclusion of Dr. Abram's standard of care testimony only on the ground that Dr. Abram does not meet the active clinical practice requirement, and accordingly the analysis focuses solely on this statutory requirement.[4]

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[4] Nonetheless, it is worth noting that the knowledge requirement is plainly satisfied in this case. Under Virginia Code § 8.01-581.20(A), Dr. Abram is entitled to the presumption that he "know[s] the statewide standard of care in the specialty or field of medicine in which he is qualified and certified," even though he is not licensed to practice medicine in Virginia, because he meets the education and examination requirements for licensure in Virginia. Va. Code § 8.01-581.20(A); *see also* Pl.'s Ex. B (letter from Virginia Department of Health Professions determining that Dr. Abram's credentials meet the educational and examination requirements for licensure in Virginia). Moreover, Dr. Abram's training and specialization in pain management, and his experience with administering epidural steroid injections, demonstrate his competence. *See* Pl.'s Ex. A. Defendants here do not contest the application of this presumption and do not attempt to rebut it. *See Wright*, 593 S.E.2d at 313 ("Dr. Kaye thus failed to rebut the statutory presumption . . . .").

It is also worth noting that Virginia Code § 8.01-581.20(A), as currently enacted, does away with the "same or similar community" standard, under which a plaintiff is required to "establish[] the standard of due medical care applicable to like specialists practicing *in the same locality* where the defendant practices or in a similar locality." 14B Michie's Jurisprudence § 18 (emphasis added). The Supreme Court of Virginia has explained the evolution of the locality

Although the statutory language relating to the active clinical practice requirement is, on its face, fairly broad—as the witness's practice need only be in "defendant's specialty or a related field of medicine"[5]—the Supreme Court of Virginia has construed this language more narrowly.[6] Specifically, the Supreme Court of Virginia has held that the purpose of the active clinical

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rule for purposes of determining standard of care, as follows:

> The predecessor to [Virginia Code § 8.01-581.20], which changed the standard of care from a local standard to a statewide standard, was enacted following this Court's decision in *Bly v. Rhoads*, 216 Va. 645, 222 S.E.2d 783 (1976). In *Bly*, we declined to adopt a nationwide standard of care on the ground that it was a question for the legislature. Thus, Code § 8.01-581.20 and its predecessor are doubly significant: they adopt a statewide standard and implicitly reject a national standard.

*Henning v. Thomas*, 366 S.E.2d 109, 111-12 (Va. 1988). A party may, however, prove by a preponderance of the evidence that application of a local, as opposed to a statewide, standard is more appropriate. *See* Va. Code. § 8.01-581.20(A). *See generally* John Y. Richardson, Jr., *Virginia Abolishes Locality Rule in Medical Malpractice*, 13 U. Rich. L. Rev. 927 (1979) (tracing genesis of locality rule and explaining shift to statewide standard). The parties do not dispute that the appropriate standard in this case is a statewide standard.

[5] In this regard, it is important to note that Dr. Abram and Dr. Huang—both pain management specialists—have the same qualifications, namely board certification in anesthesiology with additional training and certification in pain management. *See* Transcript at 15 (May 21, 2010).

[6] Of course, in this diversity medical malpractice action, the decisions of the Supreme Court of Virginia govern issues of substantive Virginia law under *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938). *See St. Paul & Marine Ins. Co. v. Am. Int'l Speciality Lines Ins. Co.*, 365 F.3d 263, 272 (4th Cir. 2004) ("As a federal court sitting in diversity, we are obliged to apply the jurisprudence of the Supreme Court of Virginia on issues of Virginia law."). Although it is not readily apparent whether the expert qualification requirements of Virginia Code § 8.01-581.20 are substantive or procedural, courts have sensibly held that the requirements apply in diversity medical malpractice suits arising under Virginia law. *See, e.g., Peck v. Tegtmeyer*, 834 F. Supp. 903, 908 (W.D. Va. 1992), *aff'd*, No. 92-2412, 1993 U.S. App. LEXIS 37919 (4th Cir. Sept. 8, 1993) (per curiam) ("While the qualification requirements may be viewed as 'procedural' rules, they are 'intimately bound up' with a state substantive rule, the standard of care itself" and thus "are applicable in a diversity case.").

practice requirement "is to prevent testimony by an individual who has not recently engaged in the *actual performance of the procedures at issue* in a case." *Sami v. Varn*, 535 S.E.2d 172, 175 (Va. 2000) (emphasis added). To that end, in evaluating the qualifications of a proffered expert witness, it is first essential to identify the relevant medical procedure at issue. *See Wright*, 593 S.E.2d at 313. Notably, it is not necessary for the witness to have performed the precise procedure "with the same pathology in all respects as gave rise to the alleged act of malpractice at issue" in order to satisfy the active clinical practice requirement. *Id.* at 314. This rigid interpretation of the statute has been expressly rejected, and instead the Supreme Court of Virginia directs courts to consider "the context of the actions by which the defendant is alleged to have deviated from the standard of care." *Id.*; *see also Hinkley v. Koehler*, 606 S.E.2d 803, 807 (Va. 2005) (holding that both the knowledge and active clinical requirements must be analyzed in context). Accordingly, in *Wright*—a case in which the defendant allegedly breached the standard of care by unintentionally stapling the plaintiff's bladder in the course of removing a nearby cyst on the plaintiff's urachus—the Supreme Court of Virginia held that a standard of care expert met the active clinical practice requirement where that expert had used a stapler to remove cysts *near* the bladder, but not from the urachus itself.[7] *See Wright*, 593 S.E.2d at 314. This experience was sufficient to satisfy the active clinical practice requirement because the relevant medical procedure at issue was "laparoscopic surgery in the female pelvic area near the bladder involving a surgical stapler," not the removal of a urachal cyst with a stapler. *Id.* at 313.

In addition to requiring a contextual inquiry into whether the expert witness has actually

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[7] The urachus, according to the Supreme Court of Virginia, is "'[a]n epithelioid cord surrounded by fibrous tissue extending from the apex of the bladder to the umbilicus.'" *Wright*, 593 S.E.2d at 309 n.1 (quoting Taber's Cyclopedic Medical Dictionary 2180 (19th ed. 2002)).

performed the procedures at issue, there must be a showing that the expert witness has provided direct patient care. *See Jackson*, 671 S.E.2d at 169 (excluding witness because "he did not provide any direct patient care"); *Hinkley*, 807 S.E.2d at 807. In the context of a pregnant patient, the Supreme Court of Virginia has held that "direct patient care" entails "directly car[ing] for, provid[ing] treatment or management to, or mak[ing] [delivery] decisions." *Id.* Excluded from this, by contrast, are teaching or consulting activities. *See id.* ("In the context of the alleged negligence at issue, Dr. Greenhouse's work as a teacher and consultant did not satisfy the active clinical practice requirement . . . .").

These principles, applied here, compel the conclusion that Dr. Abram had an "active clinical practice in either the defendant's specialty or a related field of medicine within one year of the date of the alleged act or omission forming the basis of the action." Va. Code § 8.01-581.20(A). To begin with, it is worth emphasizing that the first relevant procedure to which Dr. Abram intends to testify is the *decision* to perform a thoracic transforaminal epidural steroid injection, and not the *administration* of that procedure. *See* Defs.' Ex. 1, at 11-12 ("The standard of care involves two issues. One is [Dr. Huang's] choice of procedure . . . ."). Dr. Abram clearly has provided patients with this care directly under the standard set forth in *Hinkely*, and has done so within one year of the alleged malpractice, which occurred on June 1, 2006. Indeed, he specifically avers that between 2005 and 2007, he "participated in *treating* patients with acute herpes zoster" and "*supervised* pain fellows and residents about the treatment of acute herpes zoster patients during that time." Pl.'s Ex. A ¶¶ 5, 7 (emphases added). These activities, which

were not limited to teaching and consulting, constituted an active clinical practice.[8]

In response, defendants cite *Lawson v. Elkins*, 477 S.E.2d 352 (Va. 1996), to argue that even though Dr. Abram intends to testify that the *decision* to perform a transforaminal epidural steroid injection failed to meet the standard of care, Virginia Code § 8.01-581.20 nonetheless requires Dr. Abram to have actually *performed* this injection within one year of the alleged malpractice. This argument misapprehends the *Lawson* decision. In that case, the trial court excluded the plaintiff's standard of care expert, who intended to testify on whether the plaintiff was a suitable candidate for a surgical disk excision by a procedure called chemonucleolysis, but not the performance of the procedure itself. Although the Supreme Court of Virginia ultimately affirmed the exclusion of the plaintiff's expert, noting that he "has never performed a chemonucleolysis procedure on a patient," it is clear that the exclusion was based on the expert's *lack of knowledge*, and not on the expert's failure to have an active clinical practice, a separate and distinct statutory requirement. *See Lawson*, 477 S.E.2d at 511 ("[T]he record reveals that Dr. Jackson has a very limited knowledge of chemonucleolysis."). As discussed *supra*, however, the knowledge requirement of Virginia Code § 8.01-581.20 is not at issue in this case, and therefore *Lawson* is distinguishable on this ground. Furthermore, in a decision following *Lawson*, the Supreme Court of Virginia found the distinction between making a treatment decision and performing the chosen procedure to be relevant to the active clinical practice analysis. *See Wright*, 593 S.E.2d at 313 ("If Wright's theory of the case were pled to claim . . . that removing the urachal cyst with a stapler, in and of itself, was below the standard of care, Dr. Kaye's

[8] Again, it is worth noting that both Dr. Abram and Dr. Huang serve as medical directors in pain clinics and have the same qualifications. *See supra* note 5.

argument might prevail."). On this record, therefore, there is no basis for concluding that Dr. Abram did not maintain an active clinical practice, which includes deciding which pain treatments are suitable for patients with shingles, and accordingly Dr. Abram's opinion and testimony as to the relevant standard of care is admissible under Virginia Code § 8.01-581.20.

The same result obtains with respect to Dr. Abram's opinion on the standard of care governing plaintiff's failure to obtain informed consent claim. On this subject, Dr. Abram intends to testify that "Dr. Huang needed to inform the patient that this particular approach"—namely performing a thoracic transforaminal epidural steroid injection—"carried a higher risk of paralysis than other possible approaches" because steroids were involved. Defs.' Ex. 1, at 47; *see also id.* at 31 (agreeing that "standard of care required of [sic] Dr. Huang to have some additional conversation with Ms. Dunston above and beyond what he had *because he was using steroids*" (emphasis added)). Accordingly, to satisfy the active clinical practice requirement, Dr. Abram must have obtained informed consent from a patient in the context of performing a steroid injection. Uncontradicted testimony makes clear that Dr. Abram in fact did so in the course of his pain treatment practice. For instance, Dr. Abram avers in his affidavit that his "active clinical practice" includes administering steroid injections and "engag[ing] the patient in an informed consent discussion." Additional support is found in his deposition testimony, in which he specifically discusses his practice of regularly warning patients of the risk of paralysis associated with epidural steroid injections. *See* Defs.' Ex. 1, at 32-33. Thus, on this record, there is also no basis to conclude that Dr. Abram lacks an active clinical practice with respect to obtaining informed consent for epidural steroid injections, and accordingly his testimony as to the standard of care for informed consent is admissible under Virginia Code § 8.01-581.20.

## III.

Defendants also seek exclusion of Dr. Abram's causation theory, namely that steroid particulate entered a radicular artery, where it embolized small blood vessels causing ischemia and paralysis in plaintiff. Exclusion is warranted, according to defendants, on the ground that Dr. Abram's causation opinion fails to meet the requirements of Rule 702, Fed. R. Evid., and the standard set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Notably, the Federal Rules of Evidence, and not Virginia law, govern the admissibility of Dr. Abram's causation opinion.[9]

Rule 702, Fed. R. Evid., states that an expert witness may present opinion testimony "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Although the Supreme Court in *Daubert* recognized that testing, peer review, the existence of a known error rate or controlling standards, and the general acceptance of the

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[9] It is well-settled that the Federal Rules of Evidence control in diversity cases, except in limited circumstances not at issue on defendants' motion to exclude Dr. Abram's *causation* opinion. *See, e.g., Scott v. Sears, Roebuck & Co.*, 789 F.2d 1052, 1054 (4th Cir. 1986) ("Unlike evidentiary rules concerning burdens of proof or presumptions, the admissibility of expert testimony in a federal court sitting in the diversity jurisdiction is controlled by federal law. State law, whatever it may be, is irrelevant."). The exception arises where, unlike here, "a question of admissibility of evidence is so intertwined with a state substantive rule that the state rule . . . will be followed in order to give full effect to the state's substantive policy." *Hottle v. Beech Aircraft Corp.*, 47 F.3d 106, 110 (4th Cir. 1995) (citation and quotation marks omitted, ellipses in original); *see also* 9A Wright & Miller, Federal Practice and Procedure § 2405, at 213 (3d ed. 2008). Notably, this principle does support the application of Virginia Code § 8.01-581.20 to the separate evidentiary question, also raised in defendants' motion, whether Dr. Abram is qualified to testify on *standard of care*. *See supra* note 6. Yet, no analogous Virginia statutory provision bears on the admissibility of causation testimony in medical malpractice actions, and thus defendants' motion to exclude Dr. Abram's *causation* opinion is appropriately based on the Federal Rules of Evidence.

relevant scientific community may establish that testimony is based on "reliable principles and methods," the Supreme Court expressly cautioned that "[m]any factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test," emphasizing that "the inquiry envisioned by Rule 702 is . . . a flexible one." 509 U.S. at 592-95. Importantly, the *Daubert* inquiry focuses on the reliability of the expert's principles and methodology, rather than the conclusions generated. *See id.* at 595.

Consistent with this, the Fourth Circuit has held that differential diagnosis—the process of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated—may be "a valid foundation for an expert opinion." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999). Indeed, the Fourth Circuit joined "the overwhelming majority of the courts of appeals" in holding that "a medical opinion on causation based upon a reliable differential diagnosis is sufficiently valid to satisfy the first prong of the Rule 702 inquiry" on the ground that differential diagnosis was "a standard scientific technique." *Id.* Underlying this decision was the fact that differential diagnosis had been met with "widespread acceptance in the medical community" because it "ha[d] been subject to peer review, and d[id] not frequently lead to incorrect results." *Id.* at 262-63 (citation and quotation marks omitted). Notably, the Fourth Circuit rejected arguments that the differential diagnosis at issue in *Westberry* was unreliable because the expert (i) did not have scientific literature directly on point, (ii) relied in part on a temporal relationship between the plaintiff's exposure to the allegedly harmful substance and his sinus injury, and (iii) did not rule out every possible alternative cause of the injury. *See id.* at 265-66. These arguments, according to the Fourth Circuit, went only to the weight of the expert's testimony, not to its admissibility. *See id.* at 265.

These principles, applied here, point persuasively to the conclusion that Dr. Abram's causation opinion is reliable and meets the requirements of Rule 702, Fed. R. Civ. P., as he performed a differential diagnosis by considering "the relevant, available evidence, including the patients' signs and symptoms, the temporal element of the injury, physical examinations that have been performed, the medical literature (if indicated), and [his] education, knowledge, and experience." Pl.'s Ex. A ¶22. In particular, the record evidence establishes that Dr. Abram took into account at least the following facts: (i) that it is well accepted within the anesthesiology and pain medicine communities that particulate matter contained in epidural steroid injections can cause occlusion to an artery, as evidenced by the Tiso article;[10] (ii) that, with respect to plaintiff, "[t]he pain and paralysis came on extremely rapidly," indicating that her injury was produced by an intra-arterial injection, and not an intrathecal injection;[11] and (iii) that a medical study concerning pigs concluded that "arterial injection of particular matter into a spinal artery produced spinal cord injury."[12] Ultimately, Dr. Abram states that there is "a significant amount of evidence" to support his opinion that particulate matter injected into an artery caused plaintiff's paralysis for four principal reasons:

> number one, . . . when you do these injections you are very close to the arterial supply to the spinal cord. Number two, it's been shown that the material that you're injecting is large enough to occlude small arteries. Number three, there is

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[10] *See* Pl.'s Ex. A ¶ 11; Defs.' Ex. 1, at 59-60. The full citation to the Tiso article, in addition to the citation for another article, is provided in Dr. Abram's expert report. *See* Pl.'s Ex. C.

[11] Defs.' Ex. 1, at 59.

[12] Defs.' Ex. 1, at 61. It is worth noting that while Dr. Abram testified that he did not review this study in connection in forming his conclusions in this case, he had read the abstract of the study within the last year and referenced the study during his deposition. *See id.* at 60, 65.

> no other logical explanation for these injuries. Number four, several cases now have shown edema and changes in the spinal cord following injections of this type.

Defs.' Ex. 1, at 62-63. Moreover, during his deposition Dr. Abram competently explained why other potential causes identified by plaintiff's counsel were unlikely to have caused plaintiff's injury. *See, e.g., id.* 59 (ruling out intrathecal injection because this would not have caused painful paralysis, and ruling out injection into nerve root and dorsal root ganglion because this would have produced localized pain and injury); *id.* at 65-67 (ruling out arterial spasms for three reasons); *id.* at 68-69 (stating that allergic reaction was unlikely because plaintiff's suffering immediate pain was inconsistent with allergic reaction).

In response, defendants argue that Dr. Abram's causation theory is unreliable because it has not been tested, peer-reviewed, or generally accepted in the medical community. This argument is unpersuasive for two reasons. First, it attacks the *substance* of the causation opinion, rather than the *method* used to generate the opinion, namely a differential diagnosis. On this point, the Supreme Court has made clear that "[t]he focus [of the *Daubert* inquiry], of course, must be solely on the principles and methodology, not the conclusions that they generate." *Daubert*, 509 U.S. at 595. And as discussed *supra*, the Fourth Circuit, in addition to the "overwhelming majority of courts of appeals," have found reasoned differential diagnosis to be a reliable *method* under Rule 702, Fed. R. Evid.[13] Second, defendants' argument also fails because

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[13] *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999); *see also Feliciano-Hill v. Principi*, 439 F.3d 18, 25 (1st Cir. 2006); *Zuchowicz v. United States*, 140 F.3d 381, 387 (2d Cir. 1998); *Heller v. Shaw*, 167 F.3d 146, 154-55 (3d Cir. 1999); *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 178 (6th Cir. 2009); *Ervin v. v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007); *Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008); *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057 (9th Cir. 2003); *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1237 (10th Cir. 2004); *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d

it places dispositive weight on the *Daubert* factors, despite the Supreme Court's admonition against doing so. *See, e.g., Daubert*, 509 U.S. at 594 (" The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised."). Accordingly, the Fourth Circuit has upheld expert testimony even in the absence of supporting scientific literature where, as here, "such evidence is not always available, or necessary to demonstrate that a substance is [harmful] to humans." *Westberry*, 178 F.3d at 264. This principle is apposite here, as it would be nonsensical—and indeed unethical—to test Dr. Abram's causation theory on human subjects by producing spinal cord injuries and/or paralysis. *See* Pl.'s Ex. A ¶13. This alone explains the dearth of medical literature recording the results of such experiments.

Accordingly, Dr. Abram's causation opinion—the product of a reasoned differential diagnosis—satisfies the requirements of Rule 702, Fed. R. Evid., and the standard set forth in *Daubert*.

## IV.

In sum, because Dr. Abram had an active clinical practice in which he performed the relevant medical procedure at issue in this case—namely (i) deciding whether to administer a thoracic transforaminal epidural steroid injection to a patient with shingles, and (ii) obtaining informed consent for epidural steroid injections—Dr. Abram satisfies the statutory requirements of Virginia Code § 8.01-581.20 and may testify as an expert regarding the standard of care for

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1245, 1253 (11th Cir. 2010); *Ambrosini v. Labarraque*, 101 F.3d 129, 140-41 (D.C. Cir. 1996). Only the Fifth Circuit does not appear to have held that differential diagnosis is reliable under Rule 702, Fed. R. Evid., and *Daubert*.

these medical procedures. In addition, Dr. Abram's causation theory—arrived at by a reasoned differential diagnosis that considered, *inter alia*, the circumstances of plaintiff's injury and relevant medical literature, while ruling out other causes—is "the product of reliable principles and methods," and therefore is not excludable under Rule 702, Fed. R. Evid., and *Daubert*. Accordingly, defendants' motion to exclude Dr. Abram's opinion and testimony on standard of care and causation must be denied.

An appropriate Order has issued.

Alexandria, Virginia
May 25, 2010

/s/

**T. S. Ellis, III**
**United States District Judge**